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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,432	03/20/2001	Raymond J. Taupier JR.	15966-729 (Cura-229)	3506

30623 7590 11/19/2002

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
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EXAMINER

LAZAR WESLEY, ELIANE M

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/19/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/813,432

Applicant(s)

Taupier

Examiner

Eliane Lazar-Wesley

Art Unit

1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 21, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 29, 32, and 44-48 is/are pending in the application.
- 4a) Of the above, claim(s) 44-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 29, and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9, 11 6) ☐ Other:

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DETAILED ACTION

1. The amendment filed August 21, 2002, has been entered.

Claims 1-4, 29, 32, and newly added claims 44-48 are pending. Applicants elect the invention of Group I, drawn to isolated polypeptides, with traverse, and request that claims 44-48 be examined herein.

However, newly submitted claims 44-48 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the method of producing the polypeptide of claims 44-48 belongs to Group II, drawn to isolated nucleic acids, as defined in the restriction requirement mailed 6/21/02.

Accordingly, claims 44-48 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This requirement is made FINAL.

IDS

The form 1449 for an IDS filed 7/09/01 (Paper #3) is missing from the file. Applicant is invited to provide the form.

Claim Rejections - 35 USC § 101/112

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 29 and 32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial, specific asserted utility or a well established utility.

Claims 1-4, 29 and 32 are directed to a polypeptide of SEQ ID No:22, and variants thereof.

Applicants recite that the polypeptide of SEQ ID No:22 of the invention, that they name NOV11 (Table 1, page 5), belongs to a family of chemokine receptors. Applicants recite, at page 6, lines 28+, that NOV11 is homologous to the chemokine receptor family of proteins that are important in neuronal signal transduction and lymphocyte chemoattraction. At page 41, line 29, Applicants recite that the NOV11 polypeptide has homology (29% identity, 51% similarity) with a human chemokine receptor type I.

Applicants do not provide any data showing that NOV11 has a substantial, specific and well established utility. While they recite that NOV11 belongs to a new subfamily of the chemokine family of proteins (page 45), they do not provide any specific link between the protein of the invention and any disease, pathology, metabolic state or developmental state for example, in which NOV11 would be involved, or where its presence would be a marker for a pathological state for example.

The fact that NOV11 has structural motifs similar to a known human chemokine receptor does not provide for a specific, substantial and well-established utility, but rather is a starting point or a hint for further research aimed at defining what the specific and substantial utility of the protein could

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be. This homology actually at most means that the instant protein requires further research to have a specific and substantial utility. The invention requires further research *on* the instant protein in order to determine a specific use. Since neither the specification nor the art of record disclose any disease or conditions associated with the protein of SEQ ID No:22, the asserted utility is not substantial. As discussed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. Ct., 1966), "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is a not reward for the search, but compensation for its successful conclusion."

Claims 1-4, 29 and 32 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial, specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, even if the protein of SEQ ID No:22 would have utility, claims to variants having 15% difference in sequence to SEQ ID No:22, or to fragments of SEQ ID No:22 or of its variants, would not be enabled, absence of the description of specific motifs conferring a function to the molecule. One of skill in the art would not know how to make and use a functional variant, or a functional fragment.

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Claims 29 and 32 are to a pharmaceutical composition and are not enabled, as no pharmaceutical function has been provided for the protein.

5. Claims 1-4, 29 and 32 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim variants (claim 1), and allelic variants of SEQ ID No:22. However, Applicants only disclose in the specification a single sequence of SEQ ID No:22, and do not show that they were in possession of any variant or allelic variant thereof, nor that they were in possession of the concept of where the mutations could occur while keeping the protein functional.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 29 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy, US Patent 5,652,133.

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Murphy discloses a MIP1 α /RANTES receptor of SEQ ID No:2, which comprises a fragment of 6 contiguous amino acids identical to a fragment of SEQ ID No:22, which meets the limitations of claim 1(e). A seventh contiguous amino acid is a conservative substitution (I \rightarrow L). (see sequence comparison, attached).

8. Claims 1-4, 29 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Charo, US Patent 5,707,815.

Charo discloses a human chemokine receptor of SEQ ID No:5, which comprises a fragment of 6 contiguous amino acids identical to a fragment of SEQ ID No:22, which meets the limitations of claim 1(e). A seventh contiguous amino acid is a conservative substitution (I \rightarrow L). (see sequence comparison, attached).

9. The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Vogeli, WO 200262797 discloses a GPCR identical at position 6-287 to the instant SEQ ID No:22 at position 43-324 (see sequence comparison, attached).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

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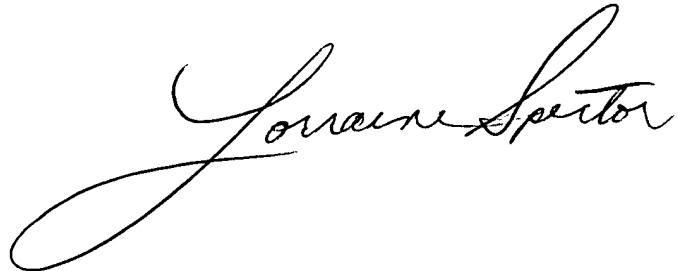
Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ELW

November 18, 2002

ew

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned to the right of the date.

**LORRAINE SPECTOR
PRIMARY EXAMINER**

12-128

DECLASSIFICATION

RESULT 5
US-08-446-669-5
Sequence 5, Application US/08446669
Patent No. 6132987
GENERAL INFORMATION:
APPLICANT: Charo, Israel
APPLICANT: Coughlin, Shaun
TITLE OF INVENTION: MAMMALIAN MONOCYTE CHEMAOTTRACTANT
TITLE OF INVENTION: PROTEIN RECEPTORS
NUMBER OF SEQUENCES: 14
CORRESPONDENCE ADDRESS:
ADDRESSEE: Cooley Godward Castro Huddleson & Tatum
STREET: 5 Palo Alto Square
CITY: Palo Alto
STATE: California
COUNTRY: USA
ZIP: 94306-2155
COMPUTER READABLE FORM:
MEDIUM TYPE: Floppy disk
COMPUTER: IBM PC compatible
OPERATING SYSTEM: PC-DOS/MS-DOS
SOFTWARE: PatentIn Release #1.0, Version #1.25
CURRENT APPLICATION DATA:
APPLICATION NUMBER: US/08/446,669
FILING DATE: May 25, 1995
CLASSIFICATION: 435
ATTORNEY/AGENT INFORMATION:
NAME: Neeley, Richard
REGISTRATION NUMBER: 30,092
REFERENCE/DOCKET NUMBER: UCAL-237/0105
TELECOMMUNICATION INFORMATION:
TELEPHONE: 415-843-5000
TELEFAX: 415-857-0663
TELEX: 380816COOLEYPA
INFORMATION FOR SEQ ID NO: 5:
SEQUENCE CHARACTERISTICS:
LENGTH: 355 amino acids
TYPE: amino acid
TOPOLOGY: linear
MOLECULE TYPE: protein
HYPOTHETICAL: NO
ANTI-SENSE: NO
US-08-446-669-5

Alzheimer's disease -

Claim 1; Page 42; 151pp; English.

XX CC The invention describes isolated NOVX (NOVX1-11) polypeptides. NOVX polypeptides are useful for treating pathology associated with NOVX polypeptide, determining the presence of or predisposition to a disease associated with altered levels of NOVX, identifying agents binding to NOVX and treatment of disorders associated with altered expression of members of chloride channel-associated proteins e.g. cystic fibrosis and congenital myotonia. NOVX proteins are useful in treatment of disorders including psoriasis, cancer, diabetes, metabolic disorders of pancreas, e.g. acute pancreatitis, abnormal growth and accumulation of mast cells in one or more organs (e.g. haemophilia, anaemia), pendred syndrome, skeletal dysplasias, disorders characterised by altered cell shape, motility, and apoptosis, ischaemic injury, hepatitis, neuroepithelial disorders, hepatic disorders (e.g. cryptogenic cirrhosis) and in the treatment of disorders of vascular smooth muscle cell differentiation, (e.g. heart failure, stroke). NOVX nucleic acids and polypeptides are useful to screen for molecules which inhibit or enhance NOVX activity or function and are useful as targets for the identifying small molecules, that modulate or inhibit e.g. neurogenesis, proliferation, motility, cell differentiation, haematopoiesis, wound healing and angiogenesis. NOV sequences are also useful for: identifying a cell or tissue type in a biological sample; amplifying DNA sequences from very small biological samples e.g. hair or skin or body fluids and as primers and probes to identify and/or clone NOVX homologues. NOVX proteins are useful immunogens to generate antibodies to monitor protein levels and modulate NOVX activity. Cells comprising the nucleic acids are useful for producing transgenic animals, for studying the function and/or activity of NOVX protein and identifying and/or evaluating modulators of NOVX protein activity. This sequence is the NOV10 amino acid sequence (gene located on chromosome 1) related to the chemokine receptor family of proteins, one of 12 NOV polypeptides described in the method of the invention.

XX SQ Sequence 372 AA;

Query Match 98.9%; Score 1853; DB 22; Length 372;
Best Local Similarity 99.7%; Pred. No. 1.2e-198;
Matches 349; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy 1 MEHTHAHLAANSSLSWSPGACGLGFVVPVYVYLLCLGLPANILTVIILSOLVARROK 60
Db 1 mehtthahlaansslswspgacglgfvpvyvylclglpaniltvilsolvarrqk 60
Qy 61 SSYNLLALAAADILVLFVDFLEDFLNMQMPQVDPKITEVLEFSSIHFTSIWITY 120
Db 61 ssynllalaaadilvlfvdfleedflnmqmpqvpdkitevlefsihftsiwity 120
Qy 121 PLTIDRITVCHPLKYHTVSYPARTKRVIVSVYITCFLTSIPYVWPNWNTEDYISTSVH 180
Db 121 pltidryiavchplkyhtvsypartkrvivsvyitcfltsipyvwpnwntedyistsvh 180
Qy 181 HVLIIWTHCFVYLPCSIIFILNSIIVYKLRKNSFLRGYSTGKTATILFTTTSIFATL 240
Db 181 hvlilwhcfvylpcsiifilnsiivylkrrksnflrgystgkttailfttsifatl 240
Qy 241 WAPRIIMILYHLYGAPIONRWLHMSDANMLALNTAINFLYCFISKRFRTMAAATL 300
Db 241 waprilmilyhlygapionrwlvhmsdanmlalntainfflycfiskrfrtmaaatl 300
Qy 301 KAFFKQKQVQFYTNHNSITSSPWISPANSHCIKMLVYQDKNGKPK 350
Db 301 kaffkqkqvpqfytnhnsitsspwispanshcikmlvyqdkngkpk 350

RESULT 3

AAU25559
ID AAU25559 standard; Protein; 287 AA.
XX
AC AAU25559;

XX DT 18-DEC-2001 (first entry)
XX DE Human G Protein-Coupled Receptor (GPCR) polypeptide #6.
XX KW Human; G-protein coupled receptor; GPCR; mental disorder; schizophrenia; attention deficit disorder; anxiety; depression; bipolar disorder;
KW neurological disorder; Huntington's disease; dementia; obesity; anorexia;
KW metabolic disorder; Parkinson's disease; Tourette's syndrome; thrombosis;
KW type 2 diabetes; cardiovascular disorder; myocardial infarction; cancer;
KW cardiomyopathy; atherosclerosis; human immunodeficiency virus; HIV;
KW viral infection; immunostimulant; neuroleptic; nootropic; tranquiliser;
KW antidepressant; anorectic; gene therapy.
XX OS Homo sapiens.
XX PN WO200162797-A2.
XX PD 30-AUG-2001.
XX PF 23-FEB-2001; 2001WO-US05676.
XX PR 23-FEB-2000; 2000US-0184247.
PR 23-FEB-2000; 2000US-0184303.
PR 23-FEB-2000; 2000US-0184304.
PR 23-FEB-2000; 2000US-0184305.
PR 23-FEB-2000; 2000US-0184397.
PR 02-MAR-2000; 2000US-0186457.
PR 03-MAR-2000; 2000US-0186810.
PR 09-MAR-2000; 2000US-0186810.
PR 13-MAR-2000; 2000US-0188064.
PR 03-APR-2000; 2000US-0188880.
PR 23-JUN-2000; 2000US-0194344.
PR 11-JUL-2000; 2000US-0213861.
PR 11-JUL-2000; 2000US-0217369.
PR 14-JUL-2000; 2000US-0218337.
PR 20-JUL-2000; 2000US-0218492.
XX (PHAA) PHARMACIA & UPJOHN CO.
XX PA Vogeli G, Wood LS, Parodi LA, Lind P;
XX PI WPI; 2001-570628/64.
XX DR N-PSDB; AAS42811.
XX PT New isolated nucleic acid encoding a new G-protein coupled receptor polypeptide for detecting receptor modulators that can treat mental disorders, such as schizophrenia, anxiety, depression, or obesity -
XX PS Claim 35; Page 72; 279pp; English.
XX Sequences AAU25554-AAU25616 represent human G-protein coupled receptor (GPCR) polypeptides of the invention. The proteins and their associated DNA sequences can be used to identify compounds which bind to GPCR polypeptides and in screening for compounds that modulate GPCR activity. By screening a human subject for the presence of mutations in GPCR DNA, a GPCR-related disorder or a genetic predisposition can be diagnosed. The sequences can also be used for treatment and prevention of mental disorders such as schizophrenia, attention deficit disorder, anxiety, depression, dementia and bipolar disorder, neurological disorders such as Huntington's disease, Parkinson's disease and Tourette's syndrome, metabolic disorders such as obesity, anorexia and type 2 diabetes, cardiovascular disorders such as thrombosis, myocardial infarction, cardiomyopathy and atherosclerosis, viral infections caused by HIV and cancers.

Sequence 287 AA;

Query Match 78.3%; Score 1467; DB 22; Length 287;
Best Local Similarity 99.3%; Pred. No. 1.4e-155;
Matches 280; Conservative 1; Mismatches 1; Indels 0; Gaps 0;

